Our STN: BL 125506/46

SUPPLEMENT APPROVAL
September 21, 2018

Bio Products Laboratory Limited
Attention: Mary Ann Lamb, PhD
Bio Products Laboratory USA, Inc.
302 East Pettigrew Street, Suite C-190
Durham, NC 27701

Dear Dr. Lamb:

We have approved your request dated March 12, 2018, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Coagulation Factor X (Human) [COAGADEX], to remove age restrictions for the currently approved indications of (1) on-demand treatment and control of bleeding episodes and (2) perioperative management of bleeding in patients with mild hereditary Factor X deficiency, and to add an indication for routine prophylaxis to prevent or reduce the frequency of bleeding episodes. Additionally, we have approved an expanded indication for perioperative management of bleeding to include patients with moderate hereditary Factor X deficiency.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT 01721681.

LABELING

We hereby approve the draft package insert labeling submitted under Amendment 20, dated September 19, 2018.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

PACKAGE AND CONTAINER LABELS

Please electronically submit final printed package and container labels that are identical to the package and container labels submitted on August 17, 2018, according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm333969.pdf.

All final labeling should be submitted as Product Correspondence to this BLA, BL 125506 at the time of use (prior to marketing) and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

We acknowledge that your ongoing Postmarketing Commitment (PMC) identified in the October 20, 2015, approval letter for STN 125506/0 will evaluate the safety and efficacy of COAGADEX for perioperative management in patients with severe and moderate hereditary Factor X deficiency undergoing major surgical procedures.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Tejashri Purohit-Sheth, MD
Director
Division of Clinical Evaluation and
Pharmacology/Toxicology
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research